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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
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Robert DEVRIES et al.	)	Group Art Unit: 3739
	)	
Application No.: 10/748,243	)	Examiner: Unassigned
	)	
Filed: December 31, 2003	)	
	)	
For: DEVICES AND METHODS FOR TISSUE INVAGINATION	)	Confirmation No.: 6999
	)	

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REQUEST FOR CORRECTED PATENT APPLICATION
PUBLICATION UNDER 37 C.F.R. § 1.221(b)

The Office published the above-identified application, as Publication No. US 2005-0149072-A1, with a publication date of July 7, 2005. The published application contains material mistakes that are the fault of the Office. Attached hereto is a copy of the relevant pages of the originally filed application (pages 2, 52, 55, and 56) and a marked-up copy of the corresponding pages (pages 1, 13, and 14) of the published application containing the mistakes.

The mistakes, which are indicated in red ink on the relevant pages of the marked-up copy of the published application attached hereto, are listed below with their corrections as follows:

- On page 1, after the title and before subtitle "FIELD OF THE INVENTION," please insert --DESCRIPTION OF THE INVENTION--.
- On page 1, the subtitle "FIELD OF THE INVENTION" should be aligned to the left and its font be changed to --Field of the Invention--.
- On page 1, the subtitle "BACKGROUND OF THE INVENTION" should be aligned to the left and its font be changed to --Background of the Invention--.
- On page 13, claim 47, line 1, "Wherein contacting" should read --wherein contacting--;
- On page 14, claim 64, line 3, "forceps couplddto" should read --forceps coupled to--;
- On page 14, claim 66, line 1, "Wherein the distal" should read --wherein the distal--; and
- On page 14, claim 75, line 5, "an inflatable member to the distal" should read --an inflatable member coupled to the distal tube--.

These mistakes are material because they may create ambiguities, affecting the public's ability to appreciate the technical disclosure of this patent application publication or determine the scope of the provisional rights that Applicants may later seek to enforce. See 37 C.F.R. § 1.221(b). For at least this reason, Applicants request that the Office correct the above-identified mistakes in the published application.

Applicants believe that no fee is due in connection with this Request. If, however, any Petition or fee is due, please grant the Petition and charge the fee to our Deposit Account no. 06-0916.

Respectfully submitted,

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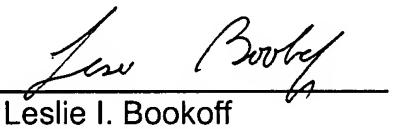
Dated: August 5, 2005

By: 

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DESCRIPTION OF THE INVENTION

Field of the Invention

[001] The present invention relates to endoscopic devices and related methods. In particular, the present invention relates to endoscopic devices and methods used in, for example, a tissue invagination procedure for treatment of Gastroesophageal Reflux Disease (GERD).

Background of the Invention

[002] Gastroesophageal reflux occurs when stomach acid enters the esophagus. This reflux of acid into the esophagus occurs naturally in healthy individuals, but also may become a pathological condition in others. Effects from gastroesophageal reflux range from mild to severe. Mild effects include heartburn, a burning sensation experienced behind the breastbone. More severe effects include a variety of complications, such as esophageal erosion, esophageal ulcers, esophageal stricture, abnormal epithelium (e.g., Barrett's esophagus), and/or pulmonary aspiration. These various clinical conditions and changes in tissue structure that result from reflux of stomach acid into the esophagus are referred to generally as Gastroesophageal Reflux Disease (GERD).

[003] Many mechanisms contribute to prevent gastroesophageal reflux in healthy individuals. One such mechanism is the functioning of the lower esophageal sphincter (LES). With reference to Fig. 1, the LES 2 is a ring of smooth muscle and increased annular thickness existing in approximately the last four centimeters of the esophagus. In its resting state, the LES creates a region of high pressure

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displacing the tissue toward the opening of the organ by displacing the distal end of the member.

42. A method according to claim 41, wherein contacting the tissue comprises holding the tissue by suction.

43. A method according to claim 42, further comprising supplying a source of vacuum to the distal end through the tubular member.

44. A method according to claim 42, wherein holding the tissue includes holding the tissue through a suction opening of the distal end of the tubular member.

45. A method according to claim 42, wherein the distal end of the tubular member comprises an elongate, curved plate and a concave insert, the plate and the insert engaged to form a space therebetween.

46. A method according to claim 45, wherein the elongate plate defines at least one suction opening through which the tissue is to be held.

47. A method according to claim 42, wherein contacting the tissue further comprises grasping the tissue held by suction.

48. A method according to claim 47, wherein grasping the tissue includes grasping the tissue with a pair of jaws.

49. A method according to claim 48, further comprising actuating the pair of jaws by a cable extending from the distal end to the proximal end of the tubular member.

50. A method according to claim 42, wherein holding the tissue by suction includes holding the tissue with at least one suction cup on an outer surface of the distal end.

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62. A method according to claim 41, wherein the distal end of the tubular member comprises at least one forceps to hold the tissue, wherein contacting the tissue comprises grasping the tissue by the at least one forceps.

63. A method according to claim 62, wherein the forceps is rotatably coupled to the distal end.

64. A method according to claim 62, further comprising:

providing at least one opening in the distal end;

providing a flexible wire having the forceps coupled to a distal end of the wire; and

extending the wire having the forceps through the opening to grasp and hold the tissue.

65. A method according to claim 41, wherein contacting the tissue layer comprises holding the tissue layer by a needle.

66. A method according to claim 41, wherein the distal end of the tubular member comprises at least one rotating member configured to contact the tissue, wherein contacting the tissue comprises bringing the rotating member in contact with the tissue and displacing the tissue comprises rotating the at least one rotating member.

67. A method according to claim 41, wherein the distal end of the tubular member comprises a rotatable arm configured to rotate relative to the axis of the tubular member, at least one end of the rotatable arm configured to contact the tissue when the rotatable arm rotates relative to the axis of the tube, wherein contacting the tissue comprises rotating the rotatable arm.

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68. A method according to claim 67, wherein at least one end of the rotatable arm comprises a sharp edge.

69. A method according to claim 41, wherein the tissue is esophageal tissue and the organ is a stomach.

70. A method according to claim 41, wherein the displacing the tissue layer includes stretching the tissue proximate to the tissue to be invaginated.

71. A method according to claim 70, further comprising:

extending the distal end of the tubular member beyond the tissue to be invaginated into the opening of the organ, the distal end including an expandable portion for applying a force to stretch a tissue of the organ and thereby invaginate the tissue toward the opening of the organ, and

expanding the expandable portion to invaginate the tissue to be invaginated toward the opening of the organ.

72. A method according to claim 69, wherein the expandable portion of the distal end is a balloon.

73. A method according to claim 71, further comprising holding tissue proximal to the tissue to be invaginated prior to expanding the expandable portion.

74. A method according to claim 73, wherein the tissue proximal to the tissue to be invaginated is held by a radially expandable balloon.

75. A device to cover a distal end of an endoscopic instrument, the device comprising:

a distal tube having a lumen sized to receive an endoscope;

an inflatable member coupled to the distal tube;

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DESCRIPTION OF THE INVENTION

DEVICES AND METHODS FOR TISSUE INVAGINATION

~~FIELD OF THE INVENTION~~ Field of the Invention

[0001] The present invention relates to endoscopic devices and related methods. In particular, the present invention relates to endoscopic devices and methods used in, for example, a tissue invagination procedure for treatment of Gastroesophageal Reflux Disease (GERD).

~~BACKGROUND OF THE INVENTION~~ Background of the Invention

[0002] Gastroesophageal reflux occurs when stomach acid enters the esophagus. This reflux of acid into the esophagus occurs naturally in healthy individuals, but also may become a pathological condition in others. Effects from gastroesophageal reflux range from mild to severe. Mild effects include heartburn, a burning sensation experienced behind the breastbone. More severe effects include a variety of complications, such as esophageal erosion, esophageal ulcers, esophageal stricture, abnormal epithelium (e.g., Barrett's esophagus), and/or pulmonary aspiration. These various clinical conditions and changes in tissue structure that result from reflux of stomach acid into the esophagus are referred to generally as Gastroesophageal Reflux Disease (GERD).

[0003] Many mechanisms contribute to prevent gastroesophageal reflux in healthy individuals. One such mechanism is the functioning of the lower esophageal sphincter (LES). With reference to **FIG. 1**, the LES **2** is a ring of smooth muscle and increased annular thickness existing in approximately the last four centimeters of the esophagus. In its resting state, the LES creates a region of high pressure (approximately 15-30 mm Hg above intragastric pressure) at the opening of the esophagus **3** into the stomach **7**. This pressure essentially closes the esophagus **3** so that contents of the stomach cannot pass back into the esophagus **3**. The LES **2** opens in response to swallowing and peristaltic motion in the esophagus, allowing food to pass into the stomach. After opening, however, a properly functioning LES **2** should return to the resting, or closed state. Transient relaxations of the LES **2** do occur in healthy individuals, typically resulting in occasional bouts of heartburn.

[0004] The physical interaction occurring between the gastric fundus **5** and the esophagus **3** also prevents gastroesophageal reflux. The gastric fundus **5** is a lobe of the stomach situated at the top of the stomach **7** distal to the esophagus **3**. In asymptomatic individuals, the fundus **5** presses against the opening of the esophagus **3** when the stomach **7** is full of food and/or gas. This effectively closes off the esophageal opening to the stomach **7** and helps to prevent acid reflux back into the esophagus **3**. More specifically, as the food bolus is immersed in gastric acid, it releases gas which causes the fundus **5** of the stomach **7** to expand and thereby exert pressure on the distal esophagus **3** causing it to collapse. The collapse of the esophagus lumen reduces the space for the stomach acid to splash past the closed esophagus lumen and thereby protect the proximal esophagus from its destructive contact.

[0005] In individuals with GERD, the LES **2** functions abnormally, either due to an increase in transient LES relaxations, decreased muscle tone of the LES **2** during resting, or an inability of the esophageal tissue to resist injury or repair itself after injury. These conditions often are exacerbated by overeating, intake of caffeine, chocolate or fatty foods, smoking, and/or hiatal hernia. Avoiding these exacerbating mechanisms helps curb the negative side effects associated with GERD, but does not change the underlying disease mechanism.

[0006] A surgical procedure, known generally as fundoplication, has been developed to prevent acid reflux in patients whose normal LES functioning has been impaired, either as a result of GERD or other adverse effects. This procedure involves bringing the fundus wall **6** into closer proximity of the esophageal wall **4** to help close off the esophageal opening into the stomach **7**, as shown in **FIG. 2**. Traditionally, this procedure has been performed as an open surgery, but also has been performed laparoscopically.

[0007] As with any surgery, the attendant risks are great. Due to relatively large incisions necessary in the performance of open surgery, relatively large amount of blood is lost, the risk of infection increases, and the potential for post-operative hernias is high. Further, the relatively large incisions necessary in the performance of open surgery require extended recovery times for the incision to heal.

[0008] A laparoscopic procedure may involve performing laparotomies for trocar ports (penetrations of the abdominal wall), percutaneous endoscopic gastronomies (incisions through the skin into the stomach), and the installation of ports through which, for example, a stapler, an endoscope, and an esophageal manipulator (invagination device) are inserted. Under view of the endoscope, an esophageal manipulator is used to pull the interior of the esophagus **3** into the stomach **7**. When the esophagus is in position, with the fundus **5** of the stomach plicated, the stapler is moved into position around the lower end of the esophagus and the plicated fundus is stapled to the esophagus **3**. The process may be repeated at different axial and rotary positions until the desired fundoplication is achieved. This procedure is still relatively invasive requiring incisions through the stomach, which has a risk of infection. The location of the incision in the abdominal wall presents a risk of other negative effects, such as sepsis, which can be caused by leakage of septic fluid contained in the stomach.

SUMMARY OF THE INVENTION

[0009] Therefore, it is accordingly an object of the present invention to provide less invasive devices and methods for performing the fundoplication procedure. This is achieved by using an invagination device which can be endoluminally delivered through the esophagus, thereby eliminating the need for highly invasive, physiologically insulting surgical procedures.

[0010] To attain the advantages and in accordance with the purpose of the invention, as embodied and broadly described herein, one aspect of the invention provides a surgical device for holding esophageal tissue during a fundoplication procedure. The device includes a proximal member having a vacuum port connectable to a source of vacuum, a substantially flexible conduit having a proximal end connected to the proximal member and a lumen in fluid communication with the source of vacuum, and a distal member connected to a distal end of the conduit and configured to hold the esophageal tissue when suction is supplied to the vacuum port from the source of vacuum.

30. A surgical device according to claim 29, wherein the expandable portion of the distal member is a balloon.

31. A surgical device according to claim 29, further comprising means for holding tissue proximal to the tissue of the first organ to be invaginated.

32. A surgical device according to claim 31, wherein the means for holding the proximal tissue is a radially expandable balloon.

33. A surgical device according to claim 31, wherein the means for holding the proximal tissue is a grasper.

34. A device for displacing tissue of a body, comprising:

an elongated tube having a proximal end configured to extend outside of the body and a distal end configured to extend proximate the tissue; and

a distal member coupled to the distal end of the tube and having at least one rotating member, the rotating member configured to contact the tissue layer and displace the tissue in the rotating direction.

35. A surgical device for displacing tissue of a body, comprising:

an elongated tube having a proximal end configured to extend outside of the body and a distal end configured to extend proximate the tissue; and

a distal member coupled to the distal end of the tube and having a rotatable arm configured to rotate relative to the axis of the tube,

wherein at least one end of the rotatable arm is configured to contact the tissue when the rotatable arm rotates relative to the axis of the tube.

36. A surgical device according to claim 35, wherein the at least one end of the rotatable arm comprises a sharp edge.

37. A surgical device according to claim 35, further comprising an actuating member for rotating the rotatable arm.

38. A surgical device for grasping esophageal tissue of a body, comprising:

a flexible elongated tube having a proximal end configured to extend outside of the body and a distal end configured to extend proximate the esophageal tissue of the body; and

a distal member coupled to the distal end of the tube and having at least one forceps to grasp the esophageal tissue.

39. A surgical device according to claim 38, wherein the distal member comprises:

a tubular body having at least one opening; and

a flexible wire having the forceps coupled to the distal end of the wire, the wire extendable through the opening to grasp the tissue.

40. A surgical device according to claim 38, wherein the forceps is rotatably coupled to the distal member.

41. A method of invaginating tissue toward an organ having an opening, comprising:

inserting an elongated tubular member into a body passage so that a distal end of the tubular member is proximate the tissue;

contacting the tissue with the distal end; and

displacing the tissue toward the opening of the organ by displacing the distal end of the member.

42. A method according to claim 41, wherein contacting the tissue comprises holding the tissue by suction.

43. A method according to claim 42, further comprising supplying a source of vacuum to the distal end through the tubular member.

44. A method according to claim 42, wherein holding the tissue includes holding the tissue through a suction opening of the distal end of the tubular member.

45. A method according to claim 42, wherein the distal end of the tubular member comprises an elongate, curved plate and a concave insert, the plate and the insert engaged to form a space therebetween.

46. A method according to claim 45, wherein the elongate plate defines at least one suction opening through which the tissue is to be held.

47. A method according to claim 42, ~~Wherein~~ wherein contacting the tissue further comprises grasping the tissue held by suction.

48. A method according to claim 47, wherein grasping the tissue includes grasping the tissue with a pair of jaws.

49. A method according to claim 48, further comprising actuating the pair of jaws by a cable extending from the distal end to the proximal end of the tubular member.

50. A method according to claim 42, wherein holding the tissue by suction includes holding the tissue with at least one suction cup on an outer surface of the distal end.

51. A method according to claim 50, further comprising radially expanding the distal end.

52. A method according to claim 41, wherein contacting the tissue comprises grasping the tissue by frictionally engaging the tissue.

53. A method according to claim 52, wherein the distal end comprises:

a tubular body having at least one side opening; and

a needle having a barbed distal end disposed inside the tubular body and configured to extend out of the tubular body through the side opening,

wherein frictionally engaging the tissue comprises extending the needle out of the tubular body.

54. A method according to claim 52, wherein the distal end comprises:

a tubular body having a proximal portion and a distal portion;

an actuation member for axially moving the proximal portion and the distal portion relative to each other; and

a plurality of flexible wires connecting the proximal portion and the distal portion, each of the wires configured to bend radially outwardly when the proximal and distal portions are moved toward each other, each of the wires includes a friction member,

wherein frictionally engaging the tissue comprises moving the proximal and distal portions toward each other.

55. A method according to claim 54, further comprising providing a projection extending outwardly from each wire.

56. A method according to claim 52, further comprising providing at least one projection extending outwardly from the outer surface of the distal end.

57. A method according to claim 52, wherein the distal end of the tubular member is radially expandable, wherein

frictionally engaging the tissue comprises holding the tissue by radially expanding the distal end.

58. A method according to claim 52, wherein:

the distal end of the tubular member includes an axially extendable, bellow-shaped tubular portion having a plurality of the friction members;

the friction members of the tubular portion are configured to radially extend and contact the tissue when the tubular portion is contracted axially, and the tubular portion forms a substantially straight outer profile when the tubular portion is extended axially; and

frictionally engaging the tissue comprises contracting the tubular portion axially.

59. A method according to claim 52, wherein the distal end of the tubular member includes a tubular body formed of braided wire, the tubular body being radially expandable, wherein frictionally engaging the tissue comprises radially expanding the tubular body.

60. A method according to claim 59, wherein at least a portion of the tubular body includes a projection extending outwardly from the tubular body.

61. A method according to claim 52, wherein the distal end includes a plurality of wires interconnected to form an expandable anchor, wherein frictionally engaging the tissue comprises expanding the plurality of wires.

62. A method according to claim 41, wherein the distal end of the tubular member comprises at least one forceps to hold the tissue, wherein contacting the tissue comprises grasping the tissue by the at least one forceps.

63. A method according to claim 62, wherein the forceps is rotatably coupled to the distal end.

64. A method according to claim 62, further comprising:

providing at least one opening in the distal end;

providing a flexible wire having the forceps ~~couplde~~ coupled to a distal end of the wire; and

extending the wire having the forceps through the opening to grasp and hold the tissue.

65. A method according to claim 41, wherein contacting the tissue layer comprises holding the tissue layer by a needle.

66. A method according to claim 41, ~~Wherein~~ wherein the distal end of the tubular member comprises at least one rotating member configured to contact the tissue, wherein contacting the tissue comprises bringing the rotating member in contact with the tissue and displacing the tissue comprises rotating the at least one rotating member.

67. A method according to claim 41, wherein the distal end of the tubular member comprises a rotatable arm configured to rotate relative to the axis of the tubular member, at least one end of the rotatable arm configured to contact the tissue when the rotatable arm rotates relative to the axis of the tube, wherein contacting the tissue comprises rotating the rotatable arm.

68. A method according to claim 67, wherein at least one end of the rotatable arm comprises a sharp edge.

69. A method according to claim 41, wherein the tissue is esophageal tissue and the organ is a stomach.

70. A method according to claim 41, wherein the displacing the tissue layer includes stretching the tissue proximate to the tissue to be invaginated.

71. A method according to claim 70, further comprising:

extending the distal end of the tubular member beyond the tissue to be invaginated into the opening of the organ, the distal end including an expandable portion for applying a force to stretch a tissue of the organ and thereby invaginate the tissue toward the opening of the organ, and

expanding the expandable portion to invaginate the tissue to be invaginated toward the opening of the organ.

72. A method according to claim 69, wherein the expandable portion of the distal end is a balloon.

73. A method according to claim 71, further comprising holding tissue proximal to the tissue to be invaginated prior to expanding the expandable portion.

74. A method according to claim 73, wherein the tissue proximal to the tissue to be invaginated is held by a radially expandable balloon.

75. A device to cover a distal end of an endoscopic instrument, the device comprising:

a distal tube having a lumen sized to receive an endoscope;

an inflatable member coupled to the distal tube;

a sleeve configured to cover the distal end of the endoscopic instrument, the inflatable member covering a distal end of the sleeve; and

a tube having an inflation lumen in fluid communication with the inflatable member.

76. The device of claim 75, wherein the tube includes an actuation lumen having an actuator.

77. The device of claim 76, wherein the actuator is a wire that includes a loop portion surrounding the sleeve.

78. The device of claim 77, wherein the wire is configured so that pulling proximally on the wire closes the loop portion on the sleeve.

79. The device of claim 75, wherein the inflatable member is a balloon.

80. The device of claim 75, wherein the inflatable member is fixed to the sleeve along a circumference of the sleeve.

81. The device of claim 75, wherein the inflatable member surrounds at least a portion of the distal tube.

82. A method of inserting an endoscopic instrument into a tissue tract of a patient, the method comprising:

placing a protective device over a distal end of the endoscopic instrument, the protective device including a sleeve to cover the distal end of the endoscopic instrument and an inflatable member covering a distal end of the sleeve;

inflating the inflatable member; and

inserting the endoscopic instrument into the tissue tract of the patient with the inflatable member inflated.

83. The method of claim 82, further comprising inserting an endoscope through the sleeve and the inflatable member.

84. The method of claim 83, wherein the protective device includes a distal tube having a lumen sized to receive the endoscope.

85. The method of claim 82, further comprising removing the protective device from the endoscopic instrument.

86. The method of claim 82, wherein removing the protective device includes pulling the protective device proximally through a channel of the endoscopic instrument.